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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 1374**  
Chise MUKAIDANI et al. : **Docket No. 2004\_1544A**  
Serial No. 10/509,032 : **Group Art Unit Not Yet Assigned**  
Filed February 9, 2005 : **Examiner Not Yet Assigned**

A METHOD OF PROLIFERATING HUMAN  
HEPATOCYTES AND A METHOD FOR  
OBTAINING HUMAN HEPATOCYTES

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☐ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application  
PCT/\_\_\_\_\_; and/or
- ☐ each reference previously cited in prior parent application Serial No.  
\_\_\_\_\_.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, **or**

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before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

**and thus no certification and/or fee is required.**

- 1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

- (1) ☐ the certification of paragraph 2 below is provided, or  
(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and**

**the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
- b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

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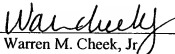
3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.
4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
  - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
  - c. ☐ the concise explanation contained in the specification of the present application at page,
  - d. ☐ the concise explanation set forth in the attached English language abstract,
  - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.
6. ☐ Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Chise MUKAIDANI et al.

By

  
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April 22, 2005

## INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)  
(Use several sheets if necessary)

Date Submitted to PTO: April 22, 2005

ATTY DOCKET NO.  
2004\_1544ASERIAL NO.  
10/509,662APPLICANT  
Chise MUKAIDANI et al.FILING DATE  
February 9, 2005

GROUP

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF<br>APPROPRIATE |
|---------------------|--------------------|------|------|-------|----------|-------------------------------|
|                     | AA                 |      |      |       |          |                               |
|                     | AB                 |      |      |       |          |                               |
|                     | AC                 |      |      |       |          |                               |

## FOREIGN PATENT DOCUMENTS

| DOCUMENT<br>NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION<br>YES NO |
|--------------------|------|---------|-------|----------|-----------------------|
| AD                 |      |         |       |          |                       |
| AE                 |      |         |       |          |                       |

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

|        |    |  |
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| /M.N./ | AG | J. A. Rhim et al., "Replacement of Diseased Mouse Liver by Hepatic Cell Transplantation", Science, Vol. 263, pp. 1149-1152, February 25, 1994.   |
| /M.N./ | AH | E. P. Sandgren et al., "Complete Hepatic Regeneration after Somatic Deletion of an Albumin-Plasminogen Activator Transgene", Cell, Vol. 66, pp. 245-256, July 26, 1991.  |
| /M.N./ | AI | J. A. Rhim et al., "Complete Reconstitution of Mouse Liver with Xenogeneic Hepatocytes", Proc. Natl. Acad. USA, Vol. 92, pp. 4942-4946, May 1995.  |
| /M.N./ | AJ | M. Dandri et al., "Woodchuck Hepatocytes Remain Permissive for Hepadnavirus Infection and Mouse Liver Repopulation after Cryopreservation", Hepatology, Vol. 34, No. 4, pp. 824-833, 2001.   |
| /M.N./ | AK | M. Dandri et al., "Repopulation of Mouse Liver with Human Hepatocytes and <i>In Vivo</i> Infection with Hepatitis B Virus", Hepatology, Vol. 33, No. 4, pp. 981-987, 2001.   |
| /M.N./ | AL | J. Petersen et al., "Liver Repopulation with Xenogenic Hepatocytes in B and T Cell-Deficient Mice Leads to Chronic Hepadnavirus Infection and Clonal Growth of Hepatocellular Carcinoma", Proc. Natl. Acad. Sci., USA, Vol. 95, pp. 310-315, January 1998. |
| /M.N./ | AM | D. F. Mercer et al., "Hepatitis C Virus Replication in Mice with Chimeric Human Livers", Nature Medicine, Vol. 7, No. 8, pp. 927-932, August 2001.   |

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|----------|-----------------|----------------|-----------------|------------|
| EXAMINER | Marcia S. Noble | /Marcia Noble/ | DATE CONSIDERED | 08/19/2008 |
|----------|-----------------|----------------|-----------------|------------|